RADIATION SAFETY BRANCH
LABORATORY PROTOCOL APPLICATION FORM

Instructions

A laboratory protocol approved by the Radiation Safety Branch is required for the following situations:

1) The use (outside of Building 21 Hot Labs) of quantities of radionuclides exceeding the "Guidelines for Maximum Activities in NIH Laboratories" (copy attached) by an Authorized User.

2) The use outside of Building 21 Hot Labs of any quantity of potentially volatile, i.e., unlabelled, radioiodine.

3) The use of quantities of radionuclides in the Hot Labs of Building 21 exceeding 25 mCi I-125 or I-131, or 10 times the Maximum Activities in NIH Laboratories for other radionuclides.

Approved protocols are valid for a two-year period, after which they may be renewed or terminated. If no work is done under an approved protocol within a two-year period, the need for the protocol will be questioned, and the responsible Authorized User will need to justify continuation of the protocol.

New Protocols

For new protocols, complete all portions of the attached application form. Send completed applications to:

Radiation Safety Officer
Building 21, Room 110

If changes (e.g., location, personnel, procedures) to the approved protocol become necessary during the year, a written amendment request must be submitted and approved before any such changes take place. It is essential that the Radiation Safety Branch protocol records be kept current.

Note: When the protocol is finalized and approved, a copy will be sent to you with the approval memorandum. You should retain this copy in your files for reference and to facilitate revisions when renewal of the protocol is required.

Protocol Renewal

For renewal of an expiring protocol you must update the first page of the application with any revisions in personnel, locations or nuclides and **you must update Sections A, B and C in accordance with the instructions attached.**

Note that any requirements established by the last Radiation Safety Branch review of the protocol must be incorporated into the body of the renewal application. If the RSB requirements are not incorporated into the renewal Sections A, B, and C, the application will be considered incomplete and returned without approval.

If you have any questions on the application process, contact the Health Physicist assigned to your area by calling 496-5774 (x8123 at the GRC).

APPLICATION FOR RADIATION SAFETY LABORATORY PROTOCOL

PROTOCOL NUMBER: _____

APPLICATION FOR (circle one): NEW PROTOCOL RENEWAL REACTIVATION AMENDMENT

AUTHORIZED USER(S):

Name _____RSB ID # _____Bldg_____Rm_____Phone_____
Name _____RSB ID # _____Bldg_____Rm_____Phone_____
Name _____RSB ID # _____Bldg_____Rm_____Phone_____
Name _____RSB ID # _____Bldg_____Rm_____Phone_____

LOCATION(S) OF PROTOCOL WORK:

BLDG_____ROOM(S)_____BLDG_____ROOMS_____

Radionuclide_____Compound_____Maximum Activity Received Per Day_____mCi
Radionuclide_____Compound_____Maximum Activity Received Per Day_____mCi
Radionuclide_____Compound_____Maximum Activity Received Per Day_____mCi
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Radionuclide_____Compound_____Maximum Activity Received Per Day_____mCi
Radionuclide_____Compound_____Maximum Activity Received Per Day_____mCi

INDIVIDUALS WHO WILL PARTICIPATE IN PROTOCOL:

Name_____RSB ID #_____	**Name_____RSB ID #_____**
Name_____RSB ID #_____	**Name_____RSB ID #_____**
Name_____RSB ID #_____	**Name_____RSB ID #_____**
Name_____RSB ID #_____	**Name_____RSB ID #_____**
Name_____RSB ID #_____	**Name_____RSB ID#_____**
Name_____RSB ID #_____	**Name_____RSB ID #_____**

Please provide information requested in Sections A through C below, then sign and date Section D.

A. Experimental Procedure

Briefly describe the chemical reactions and procedures involved in the protocol work, including physical manipulations such as centrifugation, scraping of TLC plates, freeze-drying, incubation, etc. Concentrate on those factors that relate to potential external and/or internal radiation exposure due to increased risk of dispersal, volatilization or other factors. Specify the radionuclide(s) and quantities (amount of activity) utilized in different phases of the experiment. Indicate the expected frequency of protocol work, e.g. per month or year. Justify the need for quantities of radionuclide(s) exceeding the guidelines.

B. Facilities and Equipment

Indicate which phases of the protocol work will be performed in each room listed on the first page of the application. Also, specify where source vials will be stored, and indicate where the equipment (refrigerator, centrifuge, incubator, etc.) associated with the protocol work is located. **List only those rooms in which protocol quantities of radioactive material will be used or stored.**

C. Radiation Safety Precautions

The Radiation Safety Branch has developed standard requirements for protocols involving S-35, P-32, Cr-51, Ca-45, iodinations with I-125 or I-131, and I-125 or I-131 labelled compounds. If your protocol fits into one of these categories, submit the standard requirements with your application, and document any additional precautions specific to your protocol, e.g., procedures for disposing of multi-hazard waste, in Section C. Call 496-5774 (410-558-8123 at GRC) for a copy of the requirements if one was not included with your application form.

If standard requirements do not apply to your protocol, address all radiation safety precautions (e.g., contamination monitoring, bioassay requirements, labeling requirements, waste disposal procedures, etc.) for your protocol in Section C.

D. Certification

Note that by signing below, each Authorized User agrees to comply with all requirements in the application, including any standard requirements provided by

the Radiation Safety Branch. Only those persons listed on the first page of the application are permitted to work with protocol quantities of radionuclides. Any change in location of work, personnel, or experimental procedures must be submitted in writing to the Radiation Safety Officer for review and approval.

Note also that failure to comply with the provisions detailed in this protocol as approved by the Radiation Safety Committee, or the radiation safety rules and procedures of the NIH and the U.S. Nuclear Regulatory Commission, may result in suspension of the protocol.

Upon approval, only the Authorized Users who sign below will be permitted to order and receive radionuclides for work under this protocol.

SIGNATURES:

AUTHORIZED USER _____ DATE_____

AUTHORIZED USER _____ DATE_____

AUTHORIZED USER _____ DATE_____

AUTHORIZED USER _____ DATE_____

E. Comments and Recommendations of Radiation Safety Branch Health Physicists (Class II Surveys Attached):

F. Additional Requirements of the Radiation Safety Branch and/or the NIH Radiation Safety Committee:

ACTIVITY CONTROL SYSTEM -- AUTHORIZED USERS APPROVED AFTER 10/13/03

ALL AMOUNTS IN THE TABLES ARE DECAY-CORRECTED CUMULATIVE INVENTORY

BASIC AUTHORIZATION

nuclide	default ceiling amount (mCi)	max HP ceiling amount (mCi)
H-3	22.5	45
C-14	12	24
P-32	9	18
P-33	15	30
S-35	15	30
Ca-45	12	24
Cr-51	15	30
Fe-55	15	30
I-125	3	6

ADVANCED AUTHORIZATION*

CEILING AMOUNTS ARE ZERO UNTIL THE AREA HP APPROVES THE USE OF ANY GIVEN NUCLIDE BY AN AUTHORIZED USER

nuclide	default ceiling amount (mCi)	max HP ceiling amount (mCi)
Na-24	3	6
Mg-28	1.5	3
Cl-36	12	24
K-42	13.5	27
Mn-54	9	18
Co-57	15	30
Fe-59	6	12
Co-60	1.5	3
Ni-63	15	30
Cu-67	13.5	27
Ga-67	13.5	27
As-73	15	30
Se-75	3	6
Rb-86	9	18
Y-88	1.5	3
Sr-90	3	6

nuclide	default ceiling amount (mCi)	max HP ceiling amount (mCi)
Y-90	9	18
Nb-95	12	24
Mo-99	12	24
Tc-99	13.5	27
Tc-99m	19.5	39
Ru-103	10.5	21
In-111	10.5	21
I-123	13.5	27
I-129	0	0
I-131	1.5	3
Ce-141	12	24
Gd-153	12	24
Sm-153	12	24
Lu-177	12	24
Re-186	12	24
Au-198	9	18
Hg-203	7.5	15

*** Each isotope in this list is individually approved for an AU who wishes to order it. They would be assigned the default ceiling for that nuclide upon HP approval.**

- **A protocol is REQUIRED to possess more than the max HP ceiling amount**
- **The following positron-emitting isotopes require protocols for any amount ordered:**

  C-11, N-13, O-15, F-18, Na-22, Cu-64, Zn-65, Ga-68, Br-76, Rb-82, Tc-94m, I-124

- **All unbound iodines require a protocol or use of the DRS Hot Lab Facility**
- **All alpha-emitting radionuclides require a protocol!**
- **To order a nuclide not on either list, contact your Area Health Physicist (6-5774**

Last modified: 1/13/04